T-1108 – TOPS Wording for Participant Information Sheet (PIS)

Some trials involving healthy volunteers will require the use of The Over-Volunteering Prevention System (TOPS). Where TOPS is used in UHL-sponsored research, the PIS must include an explanation about the requirement for volunteers to be registered in TOPS.

Suggested wording for the PIS is as follows:

> *'You must not take part in too many studies because it is not good for you. To help research locations protect volunteers, the Health Research Authority keep a database of healthy volunteers and when they take part in studies, called 'TOPS'.*
>
> *We will enter the following information into the TOPS database:*
>
> - *your National Insurance number (if you're a UK citizen); or*
> - *your passport number and country of origin (if you're not a UK citizen); and*
> - *the date of your last dose of study medicine*
>
> *If the database shows that you are currently taking part in a study (or have recently finished), we will check if it is safe for you to take part in another study and let you know.*
>
> *If you withdraw from the study before you receive any study medicine, the database will show that you never received a dose.*
>
> *Only staff at* **[INSERT NAME OF RESEARCH LOCATION]** *and other UK medicines research locations can use the database. We may contact other locations, or they may contact us, to check your details.*
>
> *We will not keep your data for any longer than two years. If we need to contact you about a study after you have finished it, but we can't because you have moved or lost contact with your GP, we might be able to trace you through the information in the database'.*